MINIATURE BONE-ATTACHED
SURGICAL ROBOT

This application claims priority to United States Provisional Application Serial No. 60/220,155, filed July 24, 2000.

TECHNICAL FIELD

The present invention relates to a robotic device. Particularly, this invention relates to a robotic device that attaches to a bone of the patient and aids or performs surgical procedures.

BACKGROUND OF THE INVENTION

Generally, robots are used in many different industries for many different applications. One industry, for example, is the medical industry that uses robots in applications including assisting the surgeon during surgical procedures. Robots are especially suited for some surgical tasks because they can be constructed to be very steady, computer controlled, and precise in their movements. Characteristics such as these can be especially helpful during surgery on sensitive areas, such as, for example, the vertebral column but are applicable throughout the body.

Typical vertebral column surgical procedures include vertebral fusion, insertion of medical devices such as pedicle screws, discography, percutaneous discectomy, or the like. These procedures typically require a large invasive operation that exposes the patient to a high risk of infection, excessive trauma, fluid loss, post operative pain, scaring, and a lengthy recovery time. Some difficulties relating to surgery on the vertebral column include micro-movement of the vertebral column during the operation, inherently small target objects of the procedure such as the

5   pedicles, extremely delicate nearby nerve tissue, and limited operating room space

because large equipment is needed to aid in the procedure, such as C-arm X-ray

devices. Furthermore, the patient and operating room staff are exposed to large doses

of radiation because these procedures require repeated X-raying and/or fluoroscoping

of the surgical site so the surgeon can view the position of surgical tools or implants

10   relative to non-visible body parts.

A need exists for a device that can assist minimally invasive surgery with low

radiation exposure while allowing the surgeon to precisely align and control or

monitor the surgical procedure. Some prior art devices have attempted to accomplish

this however, these devices are either too complicated, not sufficiently accurate, or

15   consume too much operating room space.

One such device is disclosed in U.S. Patent No. 6,226,548. This device

combines a navigation system, a bone mounted apparatus, and surgical tools that

communicate with the navigation system. This apparatus primarily consists of a clamp

that attaches to the patient's spine and extends outward forming a reference arc

20   bearing emitters or a tracking means. All the surgical tools used in this procedure are

fitted with emitters or a tracking means similar to the reference arc. The surgical suite

is fitted with a navigation system capable of recognizing the emitters or tracking

means of the reference arc and surgical tools, a computer system for interpreting the

location of the tools, and a video display for the surgeon. After surgically placing the

25   clamp and reference arc on the patient a CT or MRI is taken creating a

three-dimensional image of the patient with the attached device. When the patient is

in place in the surgical suite with the attached reference arc the navigation system

locates the arc and the surgical tools and displays them, relative to each other, on the

three-dimensional CT scan.

30   While the device disclosed in the '548 patent offers some advantages in terms

of accuracy and reduced trauma, the advantages of this type of prior art device are

limited. The critical part of a surgical tool that must be monitored is the working end

of the tool, whether that be a screwdriver or a drill bit or the like. These [can not]

cannot be tracked with such prior art systems. Transmitters or emitters cannot be

35   attached to the working ends of tools so the computer must estimate the location of the

working end by locating the tool generally and extrapolating. This causes inaccuracy

5   and errors that [can not] cannot be tolerated in spinal surgery or other high accuracy

procedures where the smallest error can result in a serious and permanent outcome.

Also, prior art devices such as these are hand held by the surgeon and thus, limited in

accuracy to the surgeon's ability to hold and align the tool.

        Furthermore, when using this system, the user must be cautious to not block

10   the line-or-sight between the tool mounted emitters or receivers, the reference arc

bearing emitters or receivers, and the navigation system. This can severely limit the

ability of the surgeon or surgical team as the tool may actually limit their ability to aid

the patient. Also, while such prior art systems do reduce the incision size, they

complicate the surgical procedure. Usually a patient is brought into a surgical suite

15   ready for a procedure, the procedure is performed, completed, and the patient leaves.

However, the '548 patent system requires the patient to be put through a surgical

procedure to affix the clamp and referencing arc, then the patient is transported to a CT

or MRI, then transported back to the surgical suite in a non-sterile condition for the

substantial portion of the procedure to commence. Finally, this system has many

20   components, such as the navigation system and the computer output unit, that clutter

up the already limited space in the surgical suite.

        Therefore, there is a need in the art for a device with high precision and

accuracy that can assist the surgeon in aligning the working end of the surgical tool

such that delicate procedures can be preformed percutaneously with minimal radiation

25   exposure to both the patient and the surgical staff.

SUMMARY OF THE INVENTION

        The present invention is directed to a device and method for assisting in

surgical procedures. According to the invention, a robot is disclosed that precisely

30   positions a surgical tool with respect to a surgical site. The robot attaches to the bone

of a patient with a clamp or with wires such as K-wires. Actuators extend from the

robot base and move away from and toward the base member. This manipulates balls

that rotate within spherical swivel joints that in turn align a sleeve. A surgical tool

such as a screw driver or a drill bit is inserted through the sleeve and thus is precisely

35   aligned with a site requiring surgery.

        The present invention also includes a method for using the robot to assist in

surgical procedures. Initially, three dimensional images are taken of the patient and the surgeon performs pre-operative planning of the procedure to be done on the images. This creates parameters that will later be used to direct the robot to the location where the surgical procedure is required. The robot is then attached to the patient by the clamp or the k-wire. C-arm images are taken of the patient with the attached clamp and these images are co-registered and calibrated such that a precise image of the bone with the robot attached is generated. This image is then registered, or matched, with the three dimensional image. This is accomplished in a highly efficient and accurate manner by taking small windows of the images where the surgery is to take place and registering these small portions. The small windows are chosen off the images by locating the bone attached clamp and selecting a window according to pre-operative calculation of the bone-robot attachment location. After these windows are chosen and registered, the remaining bone is registered by aligning the registered windows. At this point the robot is located precisely on the bone of the patient in the three dimensional image and can be manipulated by the surgeon to a pre-operative planned location for percutaneous insertion of surgical tools, medical devices, or implants.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the nature, objects, and function of the present invention, reference should be made to the following detailed description in conjunction with the accompanying drawings, in which:

FIG. 1 is an overview of an embodiment of a surgical system showing a control unit with a display, C-arm with a calibration phantom attached, and a robot used for aligning surgical tools attached to the patient according to the present invention;

FIG. 2 is a perspective view showing a miniature surgical robot attached to a bone and aligning a surgical tool in an embodiment of the invention;

FIG. 3 is a perspective view showing a clamp for attaching to a bone and adaptor for receiving a robot in an embodiment of the invention;

FIG. 4 is a cross-sectional view of FIG. 3;

FIG. 5 is a flow chart of an embodiment of the method of using the present invention;

FIG. 6 is a perspective view of an image referencing plate with three referencing markers attached;

FIG. 7 is a perspective view of a spacer used to extend the clamp; and

FIG. 8 is a perspective view showing a miniature surgical robot for aligning a surgical tool attached to a bone by K-wires in an embodiment of the invention.

Like reference numerals refer to corresponding elements throughout the several drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the illustrations and particularly to FIG. 1 it can be seen that a preferred embodiment of the present invention generally includes an image guided, robot assisted, surgical system. Included in this system generally, as shown in FIG. 1, is a bone attached surgical robot 30; a control unit 10 that matches data from CT scans and C-arm images to locate robot 30 on the patient's bone and allows a surgeon to control robot 30, through the use of a mouse, joystick, touch screen, or the like; and video display 20. Control unit 10 generally includes a [cpu] CPU and user interface communicating with display 20 and robot 30.

FIG. 2 illustrates robot 30 according to one embodiment of the present invention attached with clamp 40 to vertebra 50. Robot 30 aligns sleeve 60 through which surgical tool 70 such as a screwdriver, drill bit, Kirschner wire (K-wire), or the like can be inserted and precisely aligned with a site requiring a surgical procedure and thus, the operation can be conducted percutaneously or in traditional open procedures.

In a preferred embodiment of the invention, robot 30 includes base 35 that sits vertically on clamp adaptor 45. At least two pair of actuators 80 extend from base 35. The actuators 80 extend from the base 35 forming a fixed angle 85 between base 35 and actuator 80. This angle is generally between about 15 -90 degrees and more preferably about 45 degrees. In one preferred embodiment, the points of attachment of actuators 80 are spaced apart by about 50 mm in the Z direction and about 50 mm in the Y direction. Each actuator 80 is capable of operating independently from the other actuators 80. Actuator 80 is similar to known linear actuators and includes a housing, a motor, a lead screw, an electrical connection, and a position sensor such as an optical encoder, an LVDT, or the like. In a preferred embodiment each actuator is

5   approximately 5 mm in diameter and approximately 35 mm in length.

         The end of actuator 80 that is not fixedly attached to base 35 contains hinge

         joint 90. Hinge joint 90 links actuator 80 to rigid member 100. In a preferred

         embodiment member 100 is about 4 mm in diameter and 40 mm in length. Hinge joint

         90 permits member 100 to freely rotate through about 270 degrees on an axis that runs

10   parallel to base 35. The other end of the rigid member 100 is fixed with solid

         connection 105 to ring member 110. There is no movement between rigid member

         100 and ring member 110 at solid connection 105.

         Upper ring member 110A and lower ring member 110B, solidly connected to

         individual rigid members 100, come together at spherical swivel joint 120. Each ring

15   member 110 forms one half of an outer race of spherical swivel joint 120. Ring

         members 110 are free to rotate with respect to one another, but are held fixedly from

         separating in the Z axis direction. Contained between upper ring member 110A and

         lower ring member 110B, and free to swivel, is ball 130. Passing through ball 130 is

         sleeve 60. Sleeve 60 passes through both upper and lower balls 130, forming an

20   aligning axis through which surgical tool 70 is passed. As actuators 80 extend and

         retract, hinge joints 90 freely rotate about the Z axis and balls 130 swivel in the

         spherical swivel joints 120 formed by upper and lower ring members 110. A hollow

         axis is formed by the sleeve passing through each of upper and lower balls 130 such

         that a surgical tool 70 can be inserted through and be accurately aligned with the

25   working location.

         According to the present invention the above described robot 30 is just one

         example of a robot configured for surgical assistance that may be utilized with the

         system according to the present invention. Other robot configurations that could

         satisfy the same tasks include, for example, [a] parallel [robot] robots constructed to

30   the required dimensions[, such as that]. Such robots may be defined by their joint

         types, e.g. a universal spherical revolute (USR) robot, a revolute spherical prismatic

         (RSP) robot, or a double circular triangular (DCT) robot.

         The USR robot has three identical kinematic chains, each with two links,

         connecting the base and the moving platform. The connection at the base platform is

35   by a universal joint and the moving platform is connected by a revolute joint, then

         these two links are connected by a spherical joint.

The RSPR robot has three identical kinematic chains each with two links connecting the base and the moving platform. The lower link is connected through a revolute joint, the upper link, a prismatic actuator is attached tho the lower link with a spherical joint and to the moving platform with a revolute joint.

The DCT robot is a new structure composed of planar mechanisms, each with 3 degrees of freedom. These two planar mechanisms comprise a stationary circle and a moving triangle to theoretically provide higher orientation capacity. Further details are described in Simaan, [N., Glozman, D., and Shoham, M.:] et al., "Design Considerations of new types of Six-Degrees-of-Freedom Parallel Manipulators," IEEE International Conference on Robotics and Automation, Belgium, 1998, which is incorporated by reference herein. In general there are numerous structures of parallel robots. One skilled in the art will appreciate that any robot with multiple degrees of freedom may be utilized for surgical assistance

In a preferred embodiment of the invention, robot 30 is attached with the bone of a patient by clamp 40. As shown in FIG. 3 and 4, clamp 40 comprises bone clamping portion 42 and clamp adaptor 45. Initially, handles 210 extend from clamp 40 and allow a user to hold, align, and affix clamp 40 onto a bone of the patient. The base of the handles 210 fit over nuts 220, shown in FIG. 4, located on clamp 40. When clamp 40 is in place, the user pushes handles 210 toward each other to close jaws 230 onto the selected bone. When handles 210 are fully closed, or pushed together, a first locking (described below) occurs and clamp 40 is locked in place on the bone. The user then rotates handles 210 in a clockwise direction, turning and tightening nuts 220. Nuts 220 tighten down on threaded studs 250 and pinch clamp adaptor 45 onto bone clamping portion 42. This causes a second locking of clamp 40 into place on the bone. The base of each threaded stud 250 has a spherical mating surface 255 so that when clamp adaptor 45 is tightened down onto bone clamping portion 42 the clamp adaptor can self align itself on spherical mating surface 255 of stud 250. This allows the top surface of clamp adaptor 45 to maintain a horizontal surface for receiving the robot base 35. The handles, 210, are then removed by pulling straight up and away from the clamp 40. Protruding from the top surface of clamp adaptor 45 are connection pins 200. Connection pins 200 align with receiving holes in robot base 35 and when inserted lock robot 30 into place by some type of a snap ring

5 or spring and ball bearing or plunger ball/pin.

With reference specifically to FIG. 4, it can be seen that threaded studs 250 are embedded in levers 260. Left and right levers 260 are connected together by upper center hinge 280. The other end of levers 260 connect with respective jaws 230 through side axis hinge 270. Left and right jaws 230 are connected together by main

10 pivot 290 around which the jaws rotate. When a user pushes handles 210 together to close jaws 230, upper center hinge 280 is pushed downward and at the same time side axis hinges 270 rotate around the main pivot 290. The first locking occurs when upper center hinge 280 is pushed below the center line formed between left and right side axis hinges 270, and clamp 40 locks onto the bone. When clamp 40 is in the fully

15 closed and locked position, jaws 230 are parallel to each other and separated by a set distance. The set closing distance between jaws 230 can be altered for different bone attachment applications by exchanging re-moveable jaw inserts 240 with the same of a different thickness.

FIG. 7 illustrates spacer 900 that can be attached to the top surface of clamp

20 adaptor 45 to ensure that robot 30 remains above the working area and out of any tissue that might occur when a patient has unusual body proportions. Spacer 900 attaches to connector pins 200 of clamp adaptor 45 and provides connector pins 910, similar to connector pins 200, for robot 30 attachment to the top surface of the spacer 900.

25 Above described clamp 40 is an example of one embodiment according to the invention by which a robot may be attached to a bone for assisting in a surgical procedure. Other attachment devices can also be incorporated with a robot such as, for example, K-wire connections. FIG. 8 illustrates such a K-wire connection. K-wires 950 are inserted into the bone by standard surgical procedures. Robot base 35 contains

30 an elongated slot through which K-wires 950 are inserted. Screw 960 can then be turned and tighten pinch plate 970 against robot base 35 pinching K-wires 950 between pinch plate 970 and robot base 35 holding robot 30 tight with respect to K-wires 950 and bone 50.

FIG. 5 illustrates the registration system used to establish the position of the

35 robot on the bone. Initially there is a pre-operative step 400. This step 400 consists of taking a three-dimensional scan 410 of the patient, such as a CT or MRI scan. A

5   surgeon then performs pre-operative planning 420 on the three-dimensional scan. For

       example, if the procedure to be done is a fracture fixation, the surgeon will study the

       three-dimensional image and the condition of the bone, choose the proper implant

       from a database containing implants of all types and sizes based on the present

       application, and electronically position and insert the implant, the screw, or the like.

10   [This is known in the art, for example, as described in "Marching Cubes: a high

       resolution 3D surface reconstruction algorithm", W.E. Lorensen, H.E. Cline,

       Computer Graphics 21 (1987) 163-169 which is incorporated by reference.] The

       parameters generated by the pre-operative planning 420 are stored in the control unit

       10 for positioning the robot 30 during the actual surgical procedure.

15   In an exemplary embodiment, the three-dimensional imaging may be

       accomplished through manipulation of triangle vertices using linear interpolation of

       the acquired three dimensional data. An algorithm can be used to create triangle

       models of constant density surfaces from the three dimensional data while providing a

       high-resolution three dimensional surface construction so that the models have

20   extensive detail and accuracy. There are four steps to accomplish this, the last three

       steps being resolvable by one algorithm. The four steps are: data acquisition, image

       processing, surface construction, and display.

              The data acquisition is performed through standard medical imaging

       techniques which provide information from the patient either through computed

25   tomography (CT), magnetic resonance (MR) or single photon emission computed

       tomography (SPECT). The next step, image processing is achieved by use of

       algorithms. The surface is then constructed through a three dimensional model, this

       surface is then displayed using realistic image that provides for shading and ray

       casting.

30   An algorithm known as the marching cubes algorithm may be used to assist in

       refining the surface so that it provides a more realistic picture for the surgeon. The

       surface construction is essentially a two step process of first locating the surface,

       which corresponds to a user-specified value, and then calculating norms at each vertex

       of each triangle. This algorithm utilizes cubes created from pixels to process local

35   vertices and the intersections. First, the surface corresponding to a user specified

       value is located and triangles created, then the algorithm determines how the surface

intersects the cube that was created from the pixels. This process is accomplished by assigning the vertices of each cube a value and comparing it to the value of the surface. The process results in 256 possible ways for the surface to intersect the cube. However, two symmetries of the cube, topology and rotational symmetry, are used to reduce the number of possibilities to fourteen. After the number of cases is reduced an index is created for each of the fourteen possible cases. This index allows for the identification of surface intersections and then linear interpolation can be utilized to develop the surface. A surface of constant density has a zero gradient component along the surface tangential direction, so the direction of the gradient vector is normal to the surface. From this knowledge, the surface normal vector can be determined assuming the magnitude of the gradient vector is nonzero. Because the surface of interest is between tissues of different densities, the gradient vector is nonzero. The gradient vector is the derivative of the density function. Therefore to approximate the gradient vector, the gradient vector is estimated at the cube vertices and then linearly interpolated at the point of intersection. This estimation is accomplished using the differences of the densities at a given pixel and dividing that by the lengths of the cube edges. The calculation results in the unit normal which is then linearly interpolated to the point of intersection. The unit normal is calculated for each triangle vertex and the algorithm uses this unit normal to produce Gourad-shaded images. The marching cubes algorithm creates a surface from a three dimensional data set and has been applied to two dimension data from CT, MR, and SPECT scans to successfully give a resulting three dimensional view for medical applications. More details of the image reconstruction process are described for example in Lorensen et al., "Marching Cubes: a high resolution 3D surface reconstruction algorithm," Computer Graphics 21 (1987) 163-169 which is incorporated herein by reference.

With reference now to FIG. 1, 5, and 6 the next step is initial calibration of the C-arm 450. A phantom 320 (FIG. 1) is attached to the lens of the C-arm device 300 and a blank C-arm image is taken, step 460, FIG. 5. The phantom 320 is used to correct for the distortion associated with the C-arm image. The phantom contains several reference objects and a large number of small reference objects. The control unit automatically recognizes the reference objects and creates distortion correction maps and [calibration] calibrates intrinsic parameters to correct for the imprecise

5   C-arm image. Systems such as these <u>for calibration</u> are known in the art [and described,].

   <u>One such method for distortion correction utilizes a system which combines an x-ray camera connected to a control computer with an infrared tracking system linked to the control computer. In this method of distortion correction, the training of</u>
10   <u>distortion parameters is combined with infrared tracking. The x-ray camera is calibrated, to correct for the distortion caused by the earth's magnetic fields, such distortion is dependent on the camera's position. Using the x-ray camera infrared tracking system, there are three steps for successful camera calibration to remove the distortions. The first step calibrates the x-ray camera by use of a fixed three</u>
15   <u>dimensional coordinate system represented by a static calibration object and a second calibration object to determine the distortion properties. Distinct markers are used for each calibration object . The camera images are then smoothed and a set of connected regions in the image is obtained. Error minimization between the actual and the anticipated projections of the markers is accomplished by use of a cubic polynomial.</u>
20   <u>This step, also referred to as coupled calibration, performs an error minimization between the anticipated and actual projections of the calibration markers, it utilizes a cubic distortion model to correct the resultant bending of the straight line into an S curve. Measurements are taken between the distorted actual image point and the projected point. Although this provides for some distortion correction, still, the</u>
25   <u>camera parameters must be decoupled to correct for divergence, local minima, and the dependency of the coupled calibration on the initialization.</u>

   <u>The second step, also known as decoupled parameters, need not be done intra-operatively as the infrared system is static, and the correction can be made based upon a fixed camera placement. The image is placed in the surface of calibration dish</u>
30   <u>and the distortion parameters are determined. The correction polynomials applied are only partially cubic and are linearly dependent on the distortion parameters. The resulting function is quadratic and is solved analytically.</u>

   <u>The final step eliminates the need for intra-operative calibration and marker detection. The actual camera placement and the corresponding distortion parameters</u>
35   <u>from the earlier steps are utilized in what is referred to as the "learning mode." The "learning mode" constitutes taking pre-operative images and computing the</u>

5   corresponding distortion correction parameters by spline interpolation. The calibration

is accomplished by using a pointer tracking system and matching the pre and

intra-operative contours. This last step of the overall calibration method works

however, only if the intra-operative viewing angles are limited to those in close

vicinity to the pre-operative viewing angles. Further details of such a distortion

10   correction system are described , for example, in Brack et al., "Accurate X-ray

Navigation in Computer-Assisted Surgery", Proc. Of the 12th Int. Symp. On Computer

Assisted Radiology and Surgery, H. Lemke, et al., eds., Springer, 1998[;], which is

incorporated herein by reference.

Another method of distortion correction can be implemented for use with

15   fluoroscopic images according to a preferred embodiment of the invention.

Fluoroscopic x-ray images are frequently used in the medical field, but are plagued by

substantial distortions which must be corrected in order to effectively utilize these

images. These distortions, which include small radial distortions and scaling

deviations, are a result of both C-arm armamature deflection and orientation.

20   Fluoroscopic images must be dewarped, which may be accomplished by computing a

dewarped map from a reference image The distortion can be modeled either across the

entire image as a single function or by tessellating the image view of the field into

triangles or quadrilaterals and then computing individual distortion functions, which

are determined by using bilinear interpolation. Since the individual distortion

25   functions are more adaptable, this local method is often preferred. To determine the

distortion factors, the necessary parameters are the relative position and the orientation

of the camera with respect to the imaging plane, the focal length, the image center

location, and the image scaling and radial distortion coefficients. The relationship

between these parameters is obtained by formulating the transformation from the

30   world coordinate to the camera coordinates, transforming the three dimensional

camera coordinates into two dimensional coordinates in an ideal image and then

adding radial distortion, shifting and scale. The equations are solved for the relative

position and orientation parameters by resolving a set of linear equations. Based on

the solved parameters, the remaining parameters are derived. The least squares

35   method is then used to incorporate additional points. Since the C-arm distortion is

orientation dependent, the process must be completed for a variety of orientations,

5   focusing on the extremes to ensure correction parameters cover the entire field. More

details of the process are described, for example in Yaniv et al., "Fluoroscopic Image

Processing for Computer-Aided Orthopaedic Surgery", Proc. 1st Int. Conf. On Medical

Computing and Computer-Assisted Intervention, Lecture Notes in Computer Science

1496, Elsevier, et al., eds., 1998[; Hofstetteret], which is incorporated herein by

10   reference.

Furthermore, images may be enhanced by improvement in control and

alignment of the C-arm. This type of improvement can be accomplished by the

creation of a local coordinate system. A local coordinate system may be attached to

the surgical tool, the patient , and the C-arm. Then the coordinate system of the

15   surgical tool is converted to the coordinate system of the two dimensional C-arm

image coordinate system. The transformation between the surgical tool and the

ultimate image is provided in real-time by the various position sensors. The basis for

the transformation is a linear cone beam projection model. The conversion of the

C-arm projection from three dimensional space to two dimensional image is obtained

20   preoperatively during the C-arm calibration. The constant projection parameters of the

C-arm are acquired using a calibration probe containing steel spheres which is

equipped with LED sensors. From these sensors, the position of each sphere can be

calculated and subsequently assigned a corresponding position in the two dimensional

image. The resulting system of equations are solved using an error minimizing

25   algorithm. To further minimize errors resulting from stress-dependent deformation of

the C-arm frame, additional LEDs are mounted to track the actual camera position for

updating at the time of image acquisition. To the extent there is additional distortion

in the image intensifier-TV chain of the C-arm, resulting in stationary pin cushion

distortion, and also a small variable amount of distortion caused by magnetic fields, a

30   bilinear interpolation algorithm may be used for correction. Further details are

described in Hofstetter et al., "Fluoroscopy Based Surgical Navigation – Concept and

Clinical Applications", Proc. 11th Int. Symp. on Computer Assisted Radiology and

Surgery, H.U. Lemke, et al., eds., Springer 1997[; Tsai, R], which is incorporated

herein by reference.

35   A further method for three dimensional camera calibration utilizes a two step

technique. Utilizing this two step approach, a real constraint or equation that is only a

5   function of a subset of the calibration parameters is implemented. This reduces the dimensionality of the unknown parameter space.

       The first step computes the three dimensional orientation and position. In this part of the process the distorted image coordinates are computed from the relationship between the distance between coordinate and the image center and an uncertainty

10   scaling factor.

       From these coordinates, the translation vectors and rotation factors are calculated. Using the translation vectors and rotation factors, the rotational matrix is determined.

       The second step computes the effective focal length, distortion coefficients and

15   third dimension position. These parameters are calculated from the relationship between the calibration points, the distances and the transformation matrix and rotation matrix from the first step.

       This two step method is referred to as the "radial alignment constraint" and it is only a function of relative rotation and translation between the camera and the

20   calibration points. The method is distinguishable from other methods in that the order of the transformation from the three dimensional camera coordinate to the image coordinate is rotation followed by translation as opposed to the reverse. Another benefit of this method is that it can be completed in real time. Furthermore, this method can also be used for calibrating a camera using monoview noncoplanar points

25   and multiple viewing positions. Additional details are described in Tsai et al., "A Versatile Camera Calibration Technique for High-Accuracy 3D Machine Vision Metrology Using Off-the-Shelf TV Cameras and Lenses", IEEE Journal of Robotics and Automation, Vol. RA-3, No. 4, August 1987[, which are incorporated by reference.] which is incorporated herein by reference.

30   One of ordinary skill in the art will appreciate these aforementioned methods of calibration are exemplary and not limiting on the C-arm calibration method that may be employed by the present invention.

       Next, the patient is brought into the operating room, a small incision is made according to standard surgical practice at the site where clamp 40 is to be attached, and

35   the clamp is attached to the selected bone using handles as described above, step 462, FIG. 5. Handles 210 are then removed from the clamp 40. An image referencing plate

5   800 (FIG. 6) is attached to clamp 40, step 465, FIG. 5, by receiving holes that receive

connector pins 200. The image referencing plate 800 (FIG. 6) has three referencing

markers 810 on it that show up very clear and precise in the C-arm image. The

distance and angle between the referencing markers 810 are known such that the

C-arm image can be calibrated in a secondary calibration step, step 465, to accurately

10   represent actual size of the image. At least two, but preferably three C-arm images are

taken of the patient with the attached clamp 40 and image referencing plate 800.

These C-arm images are taken from different angles, preferably 0, 45, and 90 degrees,

step 470, FIG. 5.

In another embodiment of the present invention the secondary calibration step,

15   step 465B, can be accomplished by attaching the robot 30 to the clamp and taking

multiple C-arm images. By knowing the dimensions, or by placing referencing

markers on robot 30 and knowing the distance and angle between the referencing

markers the C-arm images can be calibrated in a secondary calibration step, step 465B.

The next step of the process is co-registration, step 500. The C-arm images are

20   transferred into the control unit10 as data, step 502. At each location an image is

taken from, the position of the C-arm is recorded, step 504, into the control unit 10.

The data of the images, step 502, and the position of the C-arm, step 504, are

correlated by knowing the position from which each images was taken, step 504, and

by aligning the referencing markers 810 (FIG. 6) from the image referencing plate 800

25   (FIG. 6). Thus, an accurate, pseudo three-dimensional image of the surgical site with

the clamp 40 attached to the bone is generated. This stage can be referred to as robot

to bone registration or co-registration.

According to a preferred embodiment of the invention, bone to bone

registration next occurs in step 600. Step 600 is a process of estimating and matching

30   the true surface contours or the objects in the images. Registration methods are either

based on geometry or intensity of the image. Geometric based registration is achieved

by finding features in the [2D] two dimensional fluoroscopic images and matching

these features with corresponding features in the [3D] three dimensional image,

acquired, for example, from a CT scan dataset, MRI image, ultrasound image or from

35   a CAD model. The features can be known landmarks (anatomical landmarks or

implanted fiducials), or contour points in the fluoroscopic image, matched with the

5   registered object's surface. An algorithm that may be used to compute the

transformation is the Iterative Closest Point (ICP) algorithm. [This algorithm is

described, for example in Besl, P. J. and McKay, N. D.] The ICP algorithm is an

iterative alignment algorithm that works in three phases: first it establishes

correspondence between pairs of features in the two structures that are to be aligned

10   based on proximity, next it estimates the rigid transformation that best maps the first

member of the pair onto the second and third, it applies that transformation to all

features in the first structure. These three steps are then reapplied until convergence is

concluded. The ICP algorithm relies on a convergence theorem. The key

differentiation between the least squares registration and the ICP is the least squares

15   generically reduces the average distance between corresponding points during each

iteration whereas the closest point determination generally reduces the distance for

each point individually. Further details on the use of the ICP algorithm are described

in Besl et al., "A Method for Registration of 3D Shapes", IEEE Trans. on Pattern

Analysis and Machine Intelligence, 1992, 14(2), 239--255, which is incorporated

20   herein by reference. The input to the algorithm are sets of back-projected rays from

the fluoroscopic images, and a model of the registered object. The algorithm

iteratively computes a transformation that approximates the ray sets to the model. For

landmark registration, a match between each ray and the corresponding landmark is·

defined before searching for the transformation. Contour registration selects a new

25   surface point to match with each ray on every iteration.

Preferably, the registration process uses two or more fluoroscopic images[, as

described in greater detail, for example,]. One method of automatic registration can be

represented by a cooperative approach between registration and segmentation of

preoperative surface models and intra-operative x-ray images. The cooperative

30   approach undertakes four steps: presegmentation, transformation, extraction, and error

minimization. Presegmentation extracts contour points. These contour points

correspond to pixels with large variations in grey-level intensity. The contour points

are organized in chains of connected pixels with like grey level intensity resultings in

automatic edge detection of an image. Then initial registration completes the

35   segmentation to extract likely contours on x-ray images. This is done by identifying

multiple pixels on anatomical landmarks and defining these pixels on x-ray images,

5   thus ensuring the same landmarks are selected on the three dimensional surface model. These two sets of matched pixels are used cooperatively to estimate the initial transformation. The automatic edge detection results in an excessive number of contour points therefore it is necessary to eliminate pixels which do not correspond to contour points that are of interest. From the automatic edge detection weight must be

10   given to each pixel in order to determine the likelihood that it is a real contour pixel; this determination is made by summing the gradient value, the size of the connected component and a distance factor. The first two components come from the x-ray image while the third depends upon information from the initial registration process. The distance calculation is performed utilizing an algorithm which minimizes energy

15   and distance to account for internal and external contours, one such algorithm that may be used is the Levenberg-Marquardt algorithm. Further details of preferred registration procedures are described in Hamadeh, et al., "Towards automatic registration between CT and X-ray images: cooperation between 3D/2D registration and 2D edge detection["], " Medical robotics and computer assisted surgery, 1995,

20   Wiley 39-[-]46[,] and Hamadeh, et al., "Automated 3-Dimensional Computed Tomographic and Fluoroscopic Image Registration", Computer Aided Surgery, 1998, 3[, which]. Both of these articles are incorporated herein by reference.

       According to [this] the registration method described above, anatomical landmarks in the images are detected and matched manually. Based on this match, an

25   approximated initial guess is computed, with ray intersections, which are [3D] three dimensional points in the registration environment, being matched with the model's landmarks. Then, the object's contour in the [2D] two dimensional image is registered with the model's surface. A likelihood estimator is used to remove outliers, or pixels not in the contour, from the sample point set. A signed distance function is defined to

30   overcome any internal contours problems. The overall in-vitro accuracy of this method can be better than 2mm.

       [In]

       While most registration processes involve multiple images, in one alternative, a single fluoroscopic image may be used [for registration, achieving]. The use of a

35   single fluoroscopic image may still achieved an accuracy of about 3mm. This single fluoroscopic image technique is based on a combinatorial search among matches of

5   three points and three rays. The match with minimal average distance for the

registration is then selected. [This alternative is] These points and rays are used to

determine two initial registrations. In such a technique, both points and lines may be

used to represent data. In the single fluoroscopic model, the three points and the three

rays are registered and from this, two three-point registrations, designated by triangles

10   can be found. From the triangle's vertices, non-linear functions can be established and

then solved for the two unknowns by applying the Levenberg-Marquardt algorithm.

From these points the line can be determined and the point-line correspondence can be

solved. The lines are then fixed while the points are permuted resulting in three points

in the back-projected lines. Horn's method is then used for the transformation into a

15   frame and the ICP algorithm is implemented to determine the best match points for the

registration. Further details of this technique are described in Tang, "Method for

Intensity-based Registration with CT Images," Masters Thesis: Department of

Computer Science, Queen University, Ontario Canada, 1999, which is incorporated

herein by reference.

20   In a further alternative according to the invention, intensity-based registration

is achieved by comparing fluoroscopic images with simulated X-rays (digitally

reconstructed radiographs, or DRR's) from an estimated position. [Such a technique is

generally] In this alternative, three types of coordinate systems are involved in the

registration process: the CT coordinate system, the world coordinate system, and the

25   radiographic coordinate system. The registration process consists of determining the

CT to world transformation matrix, also known as the volume transformation matrix.

For each radiograph, the radiograph to world transformation matrix is derived.

An iterative procedure is used to adjust the translation and orientation of the computed

tomography (CT) data in the world coordinate system until a best match with the DRR

30   is found. Next the radiographic to world transformation is accomplished. Translation,

rotation, and scaling matrices are applied to the available data to complete and validate

the registration. From these matrix calculations, the world coordinate of any voxel,

three dimensional pixel, can be calculated.

To achieve the best match between the CT and the DRR, two elements are

35   required, a cost function (the inverse of measure of similarity) and an algorithm for

minimizing the cost function. Two costs functions are considered: the cross

5   correlation of the pixel values and the magnitude of the scalar product of the gradient.
The cross correlation is a function of the Pearson's product-movement coefficient and
the number of nonvoid pixels. The gradient is a function of the product of the
gradients in the plain radiographs and the DRR weighted by the number of pixels. The
relative merit of the cost functions is analyzed in the vicinity of the stereotactic

10   registration point. The stereotactic registration error and the extent of parameter space
around the minimum devoid of local minima along the axis are the applicable criteria.
A minimization algorithm based on patient orientation during the image acquisition
and the assumption that the CT and radiographic acquisitions are such that the x-rays
are nearly parallel to the CT slices is most effective in solving the registration

15   problem.

The registration process as described in this alternative can be completed either
semi-automatically or automatically. In semi-automatic registration, a mouse driven
interface can be used to initiate the registration process and provide for the rotation
and translation of the CT parameters. Automatic registration can be accomplished by

20   utilization of biscalar algorithms for translation, complimented by Powell's algorithm
for exploration of the full six-dimensional rotation parameter. The method of
automatic registration comprises eleven steps: an eight-step orientation algorithm
followed by the three-step six-dimensional minimization algorithm. Further details are
described in Lemieux et al., "Patient-to computed-tomography image registration

25   method based digitally reconstructed radiographs", Medical Physics, 21, 1994,
1749-[-1760 and] 1760 which is incorporated herein by reference.

Another type of registration that may be implemented in the invention is
intensity based registration. Intensity based registration is utilized to develop an
improved automatic beam alignment process for frameless image-guided radiosurgery.

30   Utilizing this mode of registration, radiographs acquired during patient treatment can
be coordinated with DRRs generated from a CT study representative of hypothetical
patient positions which involve three translations and three rotations. This method of
registration has three parts: developing a means of exploring the range of possible
patient positions; identifying those elements of images that effectively capture the

35   patient pose; and using a comparison statistic or cost function for the two sets of image
feature data to indicate when the best match has been accomplished. There are three

5   ways to analyze DRRs and complete the match for this method of registration: the

matched filter area correlation; the interpolative area correlation; and the iterative

reprojection. The preferred method is the iterative reprojection because it is executed

in real time. Along with the necessary correlation corrections, the comparison

between the DRRs and the radiographs poses the problem of pattern recognition which

10   must also be resolved during registration. The image data used is referred to as feature

vectors; these vectors may be primitive or highly sophisticated. The registration

algorithm provides for an independent check on the edge detection process as well as

the region of interest. The registration algorithm employs six free parameters to

minimize the chi-statistic which is consists of the weighted vector components. The

15   minimization problem is nonlinear and solved with a hybrid algorithm that starts with

a gradient search and progresses to a Taylor series approximation. Using the iterative

reprojection method, an algorithm may be designed such that the registration process

is completely automated, reliable, and speedy, however, it is necessary to identify the

areas of interest prior to registration. Further details on such techniques are described

20   for example, in Murphy, M. "An automatic six-degree-of freedom image registration

algorithm for image-guided frameless stereotactic surgery", Medical Physics, 24(6),

June 1997[,] which [are] is incorporated herein by reference [herein].

When the camera position guess and the actual position are very close, the

original and reconstructed image are very similar. Pixel intensity information is used

25   to define a measure of similarity between the datasets. The similarity measure can

include intensity values, cross-correlation, histogram correlation, and mutual

information. The algorithm proceeds in three steps. The input is a CT data set,

intrinsic camera parameters, one or more fluoroscopic images and an initial camera

position estimate for each image. In the first step, the algorithm generates one DRR

30   for each given camera position. In the second step, a dissimilarity measure is

computed between the real and reconstructed image. In the third step, new camera

poses are computed that best reduce the dissimilarity between the images. The process

is repeated until convergence is reached. The parametric space of camera positions in

then searched incrementally from an initial configuration. The space is

35   six-dimensional (three rotations and three translations). The advantages of this

technique is that no segmentation is necessary. However, the search space is

5   six-dimensional, and can contain may local minima.

A benefit of the present invention is that it can utilize either of the above described registration methods. By utilizing the dimensions of the bone attached robot and its attachment location, the initial location of the window is a very good guess of the location and therefore the intensity based method can be utilized. Thus, according

10   to the present invention, a faster and more accurate registration process is accomplished as between the [fluorscopic and 3D] fluoroscopic and three dimensional images. This is done in step 600, and occurs very quickly and with a high degree of accuracy because the registration process is performed on small windows of the images, rather than the images as a whole. Preferably windows are selected that

15   specifically relate to the known location of the robot and/or its support member. Windows of about 20 mm by 20 mm located approximately adjacent to the clamp location, according to pre-operative calculation of the bone-robot attachment location, are selected from the C-arm (fluoroscopic) image data, step 610. For example, these windows may be selected as the area above the attached clamp 40 in the C-arm image

20   and the tip of the transverse process of the vertebra covering the area where the surgical procedure is to take place. Generally, the same windows are chosen from both the pseudo three-dimensional hybrid C-arm image, step 510, and also from the CT image [(3D](three dimensional image), step 410. The small windows chosen from the C-arm images and the CT scan image are then laid over each other and matched or

25   registered by the control unit, step 620, as described above. Focusing only on a small window of the C-arm image rather than looking for a matching anatomical landmark in the entire image, makes the process occur very fast and with the high degree of accuracy needed for precise procedures such as vertebra surgery.

Next, the remaining portion of the CT and C-arm image of the bones are

30   overlaid, the registration windows are aligned, and the remaining bone is registered, step 630. Since the windows have already been accurately registered this step occurs quickly and also with a high degree of accuracy. Now clamp 40 is located precisely on the bone, step 640, of the CT image. Next, the user attaches robot 30 to clamp 40 and thus, robot 30 is located precisely with respect to the bone, step 645.

35   After robot 30 is co-registered 500 and registered 600, its position is known relative to the patient's bone and therefore can move to align with the pre-operatively

5   picked location such that the operation can virtually take place on the control unit. The user selects a pre-operatively planned location and task from step 420 by use of a joystick, mouse, touch screen, or the like, step 710. The [Robot] robot 30 responds and moves sleeve 60 into position, step 720, such that when the user inserts a surgical tool 70 through the opening in the sleeve 60 the surgical tool 70 will be precisely

10   aligned with the location requiring the surgical procedure, step 730. The surgeon can then insert a selected surgical tool 70 and operate without opening the surgical site to see the placement of the surgical tool because the surgeon can verify the positioning of the surgical tool 70 on the control unit 10 and display 20. Thus operating percutaneously or in general open procedures, with a high degree of accuracy, low

15   trauma, small incisions, low chance of infection, and minimal exposure to radiation. A further benefit of this system is that because the robot is miniature it can be freely attached to the bone of a patient and move with the body. Therefore, the robot system does not need a dynamic referencing device to maintain orientation with the body once it is registered. This creates a more precise and less complicated system that is

20   versatile and user friendly as the surgeon can manipulate the patient into different surgical positions without disturbing the robot system.

The present invention is illustrated herein by reference to a spinal vertebra attachment. However, it will be appreciated by those in the art that the teachings of the present invention are equally applicable to other bone attachments.